FLEXIBLE ENDOSCOPIC SURGICAL INSTRUMENT FOR INVAGINATION AND FUNDOPLICATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to an endoscopic surgical instrument. More particularly, the invention relates to a flexible instrument for the transoral invagination and fundoplication of the stomach to the esophagus.

2. State of the Art

Gastroesophageal fundoplication is a procedure for the treatment of gastroesophageal reflux disease (GERD), a condition in which gastric acids are regurgitated into the esophagus resulting in esophagitis, intractable vomiting, asthma, and aspiration pneumonia. The fundoplication procedure involves wrapping the fundus of the stomach around the lower end of the esophagus and fastening it in place. Traditionally, this procedure is accomplished via open surgery with the use of sutures to secure the plicated fundus of the stomach around the esophagus without penetrating (incising) the stomach.

U.S. Patent Number 5,403,326 to Harrison et al. discloses a method of performing endoscopic fundoplication using surgical staples or two-part surgical fasteners. The procedure disclosed by Harrison et al. involves performing two percutaneous endoscopic gastrotomies (incisions through the skin into the stomach) and the installation of two ports through which a stapler, an endoscope, and an esophageal manipulator (invagination device) are inserted. Under view of the endoscope, the esophageal manipulator is used to pull the interior of the esophagus into the stomach. When the esophagus is in position, with the fundus of the stomach plicated, the stapler is moved into position around the lower end of the esophagus and the plicated fundus is stapled to the esophagus. The process is repeated at different axial and rotary positions until the desired fundoplication is achieved. While, the procedure disclosed by Harrison et al. is a vast improvement over open surgery, it is still relatively invasive requiring two incisions through the stomach. Moreover, the procedure requires the manipulation of two different tools in order to position the fundus and to secure the fundus to the esophagus.

U.S. Patent Number 5,571,116 to Bolanos et al. discloses a non-invasive treatment of gastroesophageal reflux disease which utilizes a remotely operable invagination device and a remotely operable surgical stapler, both of which are inserted transorally

through the esophagus. According to the methods disclosed by Bolanos et al., the invagination device is inserted first and is used to clamp the gastroesophageal junction. The device is then moved distally, pulling the clamped gastroesophageal junction into the stomach, thereby invaginating the junction and involuting the surrounding fundic wall. The stapler is then inserted transorally and delivered to the invaginated junction where it is used to staple the fundic wall.

Bolanos et al. disclose several different invagination devices and several different staplers. Generally, each of the staplers disclosed by Bolanos et al. has an elongate body and a spring biased anvil which is rotatable approximately 15° away from the body in order to locate the invaginated gastroesophageal junction between the body and the anvil. The body contains a staple cartridge holding a plurality of staples, and a staple firing knife. Each of the invagination devices disclosed by Bolanos et al. has a jaw member which is rotatable at least 45° and in some cases more than 90° to an open position for grasping the gastroesophageal junction. One of the chief disadvantages of the methods and apparatus disclosed by Bolanos et al. is that the stapler and the invagination device must be both be present in the esophagus at the same time. With some of the embodiments disclosed, the presence of both instruments is significantly

challenged by the size of the esophagus. In all of the embodiments, the invagination device is always laterally spaced apart from the stapler. Thus, the stapler cannot staple the invaginated tissue, per se, but can only staple tissue which is laterally adjacent to the invaginated tissue. The relatively small rotational movement of the anvil of the stapler further complicates the accommodation of tissue adjacent to the invaginated tissue. In addition, surgical staples have some inherent disadvantages as compared to other fasteners. The relatively small surface area of surgical staples allows them to pass through tissue over time, thereby unfastening the tissue and allowing the staples to migrate to other parts of the body. Bolanos et al. appears to recognize this disadvantage and proposes the application of a bolster or pledger to the tissues prior to stapling. Bolanos et al. do not explain how this can be accomplished transorally using the apparatus disclosed. In addition, while Bolanos et al. make a broad reference to other types of fasteners, the substantial size constraints imposed on the apparatus which are delivered transorally would seem to prohibit any type of fastener other than the staples shown by Bolanos et al. The actuating mechanism of the device disclosed by Bolanos et al. is somewhat awkward. In particular, the stapler anvil is biased to the open position, and it is not clear whether or not the stapler anvil can be locked in a closed position

without continuously holding down a lever. In addition, it appears that the staple firing trigger can be inadvertently operated before the anvil is in the closed position. This would result in inadvertent ejection of staples into the stomach or the esophagus of the patient.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide an endoscopic surgical instrument for invagination and fundoplication of the stomach to the esophagus.

It is also an object of the invention to provide an endoscopic surgical instrument for invagination and fundoplication of the stomach to the esophagus which is minimally invasive.

It is another object of the invention to provide an endoscopic surgical instrument for invagination and fundoplication of the stomach to the esophagus utilizing fasteners which do not require bolsters or pledgers.

It is a further object of the invention to provide an endoscopic surgical instrument for invagination and fundoplication

of the stomach to the esophagus which is delivered transorally to the surgical site.

It is an additional object of the invention to provide an endoscopic surgical instrument for invagination and fundoplication of the stomach to the esophagus which is capable of plicating tissue directly in line with invaginated tissue.

Yet another object of the invention is to provide an endoscopic surgical instrument for invagination and fundoplication of the stomach to the esophagus which is easy to use and which cannot be accidentally triggered.

In accord with these objects which will be discussed in detail below, the endoscopic surgical instrument of the present invention includes a torsionally rigid but flexible tube having a proximal end and a distal end, a grasping and fastening end effector coupled to the distal end of the tube, and a manual actuator coupled to the proximal end of the tube. The grasping and fastening end effector preferably includes a separate grasper and a separate fastener. The manual actuator is coupled to the grasper and fastener of the end effector by a plurality of flexible cables which extend through the flexible tube. The tube preferably contains a lumen for receiving a manipulable endoscope

and the end effector preferably includes a passage for the distal end of the endoscope. The end effector has a store for a plurality of male fastener parts, a store for a plurality of female fastener parts, a rotatable fastener head for aligning a male fastener part and a female fastener part with tissues therebetween, a rotatable firing member for pressing a male fastener part through the tissues and into a female fastener part, and a rotatable grasper located between the fastener head and the firing member.

According to presently preferred embodiments, the overall diameters of the flexible tube and the end effector (when the fastener head is rotated to the open position and the grasper is rotated to the closed position) do not exceed approximately 20mm (and preferably less than 16mm) so that the instrument may be delivered transorally to the fundus of the stomach. The end effector preferably includes a substantially cylindrical stationary part which houses the store of male fastener parts and the firing member. Male fastener parts are ejected by the firing member through a substantially radial port in the substantially cylindrical stationary part of the end effector. The rotatable fastener head is hingedly coupled to a distal portion of the stationary part of the end effector and is rotatable from a first (open) position wherein the fastener head is rotated distally away

from the stationary part to a second (closed) position wherein the fastener head is rotated proximally toward the stationary part. The store of female fastener parts is preferably contained within the fastener head and a female fastener shuttle on the fastener head moves a female fastener from the store into alignment with the substantially radial port when the fastener head is rotated to the closed position.

The presently preferred store for male fastener parts includes a longitudinal track arranged proximally of the rotatable firing member in which male fastener parts are arranged one behind the other. Male fastener parts are moved distally along the track by a first biasing member. According to one embodiment, the firing member includes a flange which blocks distal movement of male fastener parts while a male fastener part is being ejected. According to a presently preferred embodiment, a spring leaf with a pair of bent teeth engages the distal end of the next male fastener part in the track keeping it from moving off the track. When the firing member moves down to grab another male fastener part, the leaf is deflected allowing the next male fastener part to enter the firing member. The presently preferred store for female fastener parts includes an orthogonal chamber in which female fastener parts are stacked on top of each other and a second biasing member for moving the female fastener parts onto

the female fastener shuttle. The presently preferred female fastener shuttle is a sliding tray which is located adjacent to the store of female fastener parts. The second biasing member pushes female fastener parts into the tray and the tray moves laterally away from the store of female fastener parts when the rotatable fastener head is moved from the open position to the closed position.

The rotatable fastener head, the firing member, and the grasper are preferably each controlled by an individual cable; and the proximal actuator includes three levers, each coupled to a respective cable, for individually operating the rotatable fastener head, the firing member, and the grasper. According to a presently preferred embodiment, the manual actuator includes a lock-out feature which prevents the inadvertent firing of male fastener members until the fastener head is rotated into the proper position. The manual actuator also includes a releasable lock for locking the grasper in the closed position.

According to one embodiment, the male fastener member is a circular disk with a central upstanding barbed projection and the female fastener member is a circular disk with a central hole engageable by the barbed projection of a male fastener member. According to another, presently preferred embodiment, the female

fastener is rectangular with a central hole engageable by the barbed projection of a male fastener member. The female member is preferably provided with a plurality of weak peripheral extensions which allow the member to be held in the shuttle tray, but forcibly removed therefrom after it is coupled to a male member.

The apparatus of the invention is advantageously utilized in a fundoplication procedure. The instrument is prepared by inserting a manipulable endoscope into the proximal end of the instrument and threading the endoscope through the lumen of the flexible tube out through the end of the end effector. With the grasper closed and the rotatable fastener head in the first (open) position, the end effector is inserted into the mouth of the patient and guided down through the esophagus into the stomach with the aid of the endoscope. When the end effector is distal of the fundus (or lower esophageal sphincter), the grasper is opened and the end effector is raised toward the fundus so that the fundus and the lower end of the esophagus are located between the stationary part of the end effector and the grasper. The grasper is then closed to clamp together the tissue around the juncture of the esophagus and the fundus. With the grasper closed, the rotatable fastener head is closed, raising it up toward the fundus and lifting the fundus up against the esophagus. With the instrument in this configuration, the firing member is actuated

and a male fastener member is ejected out of the radial port, through the esophagus and the fundus, and into a female fastener member which is held by the tray in the rotatable fastener head. The firing member is then returned to its initial position moving the flange or the leaf away from the male fastener store and allowing a second male fastener to be pushed onto the second rotatable member. The rotatable fastener head is moved to the open position, releasing the female fastener, and returning the tray to the store of female fasteners to receive a second female fastener. The grasper is opened and the instrument may then be repositioned and the above procedure repeated until the desired fundoplication is achieved.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an enlarged broken perspective view of a first embodiment of a flexible endoscopic surgical instrument according to the invention with the end effector in a fully open position;

Figure 2 is an enlarged broken perspective view of the distal end of the instrument of Figure 1 with the grasper of the end effector in a closed position;

Figure 3 is an enlarged broken perspective view of the distal end of the instrument of Figure 1 with the end effector in a fully closed position;

Figure 4 is an enlarged proximal end view of the end effector removed from the instrument of Figure 1;

Figure 5 is a broken enlarged transparent side elevation view of the end effector in the fully closed position;

Figure 6 is a broken enlarged transparent side elevation view of the end effector in the fully closed position with a male fastener part ejected into a female fastener part;

Figure 7 is an enlarged side elevation view of a male fastener part according to the invention;

Figure 8 is an enlarged top view of the fastener part of Figure 7;

Figure 9 is an enlarged side elevation view of a first embodiment of a female fastener part according to the invention;

Figure 10 is am enlarged top view of the fastener part of Figure 9;

Figure 11 is an enlarged schematic view of the distal end of the instrument of Figure 1 adjacent the gastroesophageal junction in a first operative position;

Figure 12 is a view similar to Figure 11 of the instrument in a second operative position;

Figure 13 is a view similar to Figure 11 of the instrument in a third operative position;

Figure 14 is a view similar to Figure 11 of the instrument in a fourth operative position;

Figure 15 is a view similar to Figure 11 of the instrument in a fifth operative position;

Figure 16 is a side elevation view of one side of a presently preferred manual actuator in a first operative position (grasper

closed and fastener head open) with the near side of the casing removed;

Figure 17 is an isometric view of one side of the actuator of Figure 16 with the near side of the casing removed;

Figure 18 is a side elevational view of the other side of the actuator of Figure 16 with the near side of the casing removed;

Figure 19 is an isometric view of the other side of the actuator of Figure 16 with the near side of the casing removed;

Figure 20 is a view similar to Figure 16 with the actuator in a second operative position (grasper open and fastener head open);

Figure 21 is a view similar to Figure 16 with the actuator in the midpoint a third operative position (grasper closed and fastener head partially closed);

Figure 22 is a view similar to Figure 16 with the actuator in a fourth operative position (grasper closed and fastener head closed);

Figure 23 is a view similar to Figure 16 with the actuator in a fifth operative position (grasper closed, fastener head closed, and male fastener part fired);

Figure 24 is a view similar to Figure 21 of the other side of the manual actuator;

Figure 25 is a perspective view of a presently preferred embodiment of the end effector in a first operative position;

Figure 26 is a perspective view of the presently preferred embodiment of the end effector in a second operative position;

Figure 27 is a perspective view of the presently preferred embodiment of the end effector in a third operative position;

Figure 28 is a perspective view of the distal end of the presently preferred embodiment of the end effector in the third operative position;

Figure 29 is a perspective view of the proximal end of the presently preferred embodiment of the end effector in the third operative position;

Figure 30 is a perspective view of the major components of the presently preferred embodiment of the end effector in the third operative position;

Figure 31 is a perspective view of the major components of the presently preferred embodiment of the end effector in a fourth operative position;

Figure 32 is a perspective view of the stationary component and the grasper of the presently preferred embodiment of the end effector;

Figure 33 is a perspective view of the grasper component and the fastener firing component of the presently preferred embodiment of the end effector;

Figure 34 is a view similar to Figure 33 of the other side of the grasper component and the fastener firing component;

Figure 35 is a perspective view of the top side of a presently preferred embodiment of a female fastener part in the female fastener carrier;

Figure 36 is a perspective view of the bottom of the presently preferred female fastener part;

Figure 37 is a perspective view of the presently preferred female fastener part coupled to the male fastener part;

Figure 38 is a broken, partially cut away perspective view of an alternate preferred embodiment showing the firing member receiving a male fastener part;

Figure 39 is a view similar to Figure 38 from a different perspective;

Figure 40 is a view similar Figure 39 showing the firing member raised and the leaf preventing a male fastener part from moving off the track;

Figure 41 is a broken perspective view of the embodiment of Figures 38-40 showing the end effector with the firing member with a male fastener part engaged therein;

Figure 42 is a perspective view of the firing member and male fastener part engaged therein by a leaf spring;

Figure 43 is a perspective view of the firing member with the leaf spring disengaged from the male fastener part to release the male fastener part;

Figure 44 is a perspective view showing the end effector with the firing member with a male fastener part with the leaf spring disengaged from the male fastener part to release the male fastener part;

Figure 45 is a broken, partially cut away perspective view of the embodiment of Figures 38-44 showing the store of female fastener parts with a female fastener part in position to receive a male fastener part;

Figure 46 is a broken perspective view of the embodiment of Figures 38-45 showing the female fastener part shuttle in position to retrieve a female fastener part from the store of female fastener parts;

Figure 47 is a broken, partially cut away perspective view of the embodiment of Figures 38-46 showing the female fastener part shuttle in an intermediate position; and

Figure 48 is a broken, partially cut away perspective view of the embodiment of Figures 38-47 showing the female fastener part and male fastener parts coupled with the ejector spring engaging the barb of the male fastener part.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figures 1 through 4, a first embodiment of an endoscopic surgical instrument 10 includes a torsionally rigid but flexible tube 12, preferably made from polyethylene, and having a proximal end 14 and a distal end 16, a grasping and fastening end effector 18 coupled to the distal end 16 of the tube 12, and a manual actuator 20 coupled to the proximal end 14 of the tube 12. The manual actuator 20 is coupled to the end effector 18 by three flexible cables 22, 24, 26 which extend through the flexible tube 12. Each of the cables is preferably formed from an outer coil sheath 22a, 24a, 26a, and an inner pull wire 22b, 24b, 26b. The actuator 20 includes three levers 22c, 24c, 26c which are coupled to respective pull wires 22b, 24b, 26b. The tube 12 also contains a lumen 28 for receiving a manipulable endoscope 2 and the end effector 18 includes a passage 30 for the distal end 4 of the endoscope 2. Preferably, the overall diameters of the flexible tube 12 and the end effector 18 (when in the position shown in Figure 2) do not exceed approximately 20mm (and are

preferably no more than 16mm) so that the instrument may be delivered transorally through the esophagus to the fundus of the stomach.

The end effector 18 has a substantially cylindrical stationary member 31, a rotatable fastener head 40, and a grasper 42. The stationary member 31 has a relatively flexible proximal portion 32 and a relatively rigid distal portion 34. The distal portion is rigid so that a store of male fastener parts and firing member can be located therein. The length of the rigid portion depends on the number of male fastener parts desired to be stored. The distal portion 34 has a flattened part 36 which angles down toward the distal end 38 of the stationary member 31. As will be described in more detail below with reference to Figures 5 and 6, the rotatable fastener head 40 is coupled to the distal end of the flattened portion 36 and is rotatable toward and away from the flattened portion 36 as seen best in Figures 2 and 3. The rotatable grasper 42 is coupled to the distal end of the flattened portion 36 proximal of the rotatable fastener head 40 and is rotatable toward and away from the flattened portion 36 as seen best in Figures 1 and 2. The rotatable fastener head 40 is coupled to the cable 24 so that its movement is controlled by the lever 24c and the grasper 42 is coupled to the cable 26 so that its movement is controlled by the lever 26c.

Referring now to Figures 4-6, the stationary member 31 of the end effector 18 includes a store 44 for male fastener parts, e.g. 46, and a substantially radial port 48 through which male fastener parts are ejected. As will be described in more detail below with reference to Figures 7 and 8, the male fasteners have a substantially T-shaped profile and the store 44 is a substantially T-shaped track which is dimensioned to hold approximately six male fastener parts. A biasing spring 50 urges the male fasteners distally along the track into position adjacent the port 48. A rotatable firing member 52 is located adjacent to the distal end of the track 44 and is coupled to the cable 22. Thus, operation of the lever 22c (Figure 1) rotates the rotatable firing member 52 thereby ejecting a male fastener part through the port 48. A lower flange 54 on the member 52 prevents distal movement of the fastener parts in the track 44 until the member 52 is rotated back to its original position.

Referring generally to Figures 1-6, the rotatable fastener head 40 includes a store 56 for female fastener parts, e.g. 57, and a sliding tray 58 for moving female fastener parts out of the store 56. The sliding tray 58 is moved automatically by a wire link 60 which causes the tray to move away from the store 56 when the rotatable fastener head 40 is rotated from the open position (Figures 1 and 2) to the closed position (Figures 3-6). As will

be described in more detail below with reference to Figures 9 and 10, according to one embodiment, the female fastener parts are generally disk shaped and are held in a stack in the store 56. A spring 62 biases the fastener parts into the tray 58 when the rotatable fastener head 40 is in the open position. The tray 58 is dimensioned such that a single fastener part is retrieved from the stack and moved in the tray to a position opposite to the port 48 when the rotatable fastener head 40 is rotated from the open position to the closed position.

Turning now to Figures 7-10, a presently preferred male fastener part 46 has a disk shaped base 46a, a central upstanding shaft 46b, and tapered barb 46c at the end of the shaft. According to a preferred embodiment, the base is approximately 0.3 inches in diameter and approximately .040 inches thick, the upstanding member is approximately 0.140 inches tall, and the barb is approximately 0.10 inches long. A first embodiment of a female fastening member 57 is a substantially flat disk 57a, having a central hole 57b, and four radially outward extending peripheral tabs 57c-57f. Four radial strain relief slits 57g-57j are preferably provided adjacent to the hole 57b. The female fastener is approximately 0.3 inches in diameter and approximately .040 inches thick. Both the male fastener and the female fastener parts are made from biocompatible polymers. The barb 46c, the

shaft 46b, and the hole 57b are dimensioned such that the barb may be forced through the hole to lock the fastener parts together, but that once locked together, the parts will not easily separate. The peripheral tabs 57c-57f are dimensioned such that they hold the female fastener part in the sliding tray prior to being locked together with the male fastener part, but that they allow the female fastener part to be pulled out of the tray after it is locked together with the male fastener part. For example, the tabs are thin enough to bend, flex, or shear off when the female fastener part is pulled out of the tray.

As mentioned above, the instrument of the invention is advantageously utilized in a fundoplication procedure. With reference now to Figures 1, 2 and 11-15, the instrument 10 is prepared by inserting a manipulable endoscope 2 into the proximal end of the instrument and threading the endoscope through the lumen of the flexible tube 12 out through the end of the end effector 18. With the grasper 42 closed and the rotatable fastener head 40 in the first (open) position (as shown in Figures 2 and 11, the end effector 18 is inserted into the mouth of the patient and guided down through the esophagus 3 into the stomach 5 with the aid of the endoscope 2. When the grasper 42 and the rotatable fastener head 40 are distal of the fundus 7, the grasper 42 is opened as shown in Figure 12 and the end effector is raised

toward the fundus 7 so that the fundus and the lower end of the esophagus 3 are located between the stationary part 31 of the end effector and the grasper 42. The grasper 42 is closed to hold the gastroesophageal junction as shown in Figure 13. The rotatable fastener head 40 is then rotated to the closed position, raising it up toward the fundus 7 and lifting the fundus 7 up against the esophagus 3 as shown in Figure 14. With the instrument in this configuration, the rotatable firing member (52 in Figures 5 and 6) is actuated and a male fastener member 46 is ejected out of the radial port 48, through the esophagus 3 and the fundus 7, and into a female fastener member 57 as shown in Figure 15. The rotatable firing member is then returned to its original position, moving the flange 54 away from the male fastener store 44 and allowing a second male fastener to be pushed onto the second rotatable member 52. The rotatable fastener head 40 is moved to the open position, releasing the female fastener, and returning the tray to the store of female fasteners to receive a second female fastener. The grasper 42 is opened and the instrument may then be repositioned and the above procedure repeated until the desired fundoplication is achieved.

Figures 16 through 24 show a presently preferred manual actuator 100, according to the invention, which is provided with a lock-out feature to prevent the inadvertent firing of a male

fastener member before the rotatable fastener head is in the proper position and with a lockable lever for holding the grasper in the closed position. Referring now to Figures 16-20, and as seen best in Figures 17 and 19, the actuator 100 has a generally pistol-shaped housing 101 which is formed from two mating halves 102, 104. By generally pistol-shaped, it is meant that the housing has a grip portion 108 and a barrel portion 109. Three levers (106, 118, 136) and a toothed cam (122) are rotatably mounted within the housing.

The first lever 106 is mounted adjacent to the gripping portion 108 of the housing and is pivotally coupled at its upper end to the housing by a pin 110. A slotted throughbore 112 in the lever 106 is located below the pin 110. The slotted throughbore 112 receives the proximal end of cable 26 (which controls the grasper) and the cable is attached to the lever 106 by a crosspin 114. The lower end of the lever 106 is provided with a spring biased latch 116 which is operatively engageable with a notch (not shown) in the housing.

The second lever 118 is pivotally coupled at one end 120 to the proximal end of the toothed cam 122. The second lever 118 is also provided with a slotted throughbore 124 which receives the proximal end of cable 22 (which controls the fastener firing

member). The proximal end of the cable 22 is coupled to the lever 118 by a crosspin 126 in the slotted throughbore 124. The slotted throughbore 124 is located in a portion 118a of the lever 118 which is broader than an immediately adjacent portion 118b. A locking stop 113 is provided in housing half 104 (Figure 18) which blocks movement of the broad portion 118a of the lever as described in more detail below.

The toothed cam 122 is rotatably coupled to one portion 102 of the housing by a pin 128 which is located between the grip portion 108 and the barrel portion 109 of the housing. This portion of the housing is provided with a slotted wall 111 (Figure 16) through which the first and second levers 106, 118 exit the housing. The slot in the wall 111 is dimensioned to allow passage of the portion 118b of the lever 118 and may be dimensioned to prevent the passage of the broader portion 118a. The cam 122 has a distal curved slotted throughbore 130 which receives the proximal end of cable 24 (which controls the rotatable fastener head). The proximal end of cable 24 is coupled to the cam 122 by a crosspin 132 which rides in the curved throughbore 130. The cam 122 is provided with a plurality of peripheral teeth 134 which extend along a curved path from the proximal end of the cam where the lever 118 is coupled to it, to a point adjacent to the curved throughbore.

The third lever 136 is rotatably mounted above the cam 122 by a pin 138 and is provided with a plurality of radial teeth 140 which engage the teeth 134 of the cam 122.

The housing 101 is also provided with a plurality of cable guides 142 (Figure 17) in the barrel portion 109 of the housing half 102 and an endoscope receiving tube 144 (Figure 18) in the barrel portion 109 of the housing half 104. In addition, the housing halves 102, 104 are provided with longitudinal guide slots 146, 148 which engage the crosspin 132 and guide its motion in a longitudinal direction.

The operation of the actuator 100 is described in sequence with reference to Figures 16-24 and with reference to the presently preferred end effector configuration of Figures 25-31 which are discussed in more detail below. Figures 16-19 show the positions of the levers 106 and 136 when the grasper is closed and the fastener head is opened (see also Figure 25). In this position of lever 136, the lever 118 is positioned so that it is impossible to move the lever 118 to fire a male fastener. In particular, the distal location of lever 136 has caused the radial teeth 140 to rotate the cam 122 proximally which has moved the pivot point 120 of the lever 118 to a position proximal of its broad portion 118a. In order to move the lever 118, the broad

portion 118a needs to pass the stop 113 (Figure 18) which prevents its movement. In addition, since the lever 118 must rotate about the pivot point 120, the portion 118a needs to exit the slot 111 in the housing. However, as described above, the slot may be dimensioned to prevent this movement. With the levers in the positions shown in Figures 16-19, the instrument is in the proper orientation for delivery through the esophagus. It will also be appreciated that the positions and locations of the levers are easy to understand and provide intuitive indication of the positions of the parts of the end effector. For example, the lever 106 is "closed" relative to the grip 108 indicating that the grasper is closed. The lever 136 is approximately 180° forward indicating that the fastener head is rotated forward (distally) approximately 180°. The lever 118, which is most like the trigger portion of the pistol shaped actuator is raised up and out of the way where it cannot be pulled.

After the end effector is in place at the surgical site, the grasper is opened (to the position shown in Figure 26) by releasing the latch 116 and moving the lever 106 distally as shown in Figure 20; thereby moving cable 26 which is attached to the grasper 206. After the grasper has been properly positioned, the lever 106 is moved back and the latch 116 holds the grasper locked closed (in the position shown in Figure 25).

The rotatable fastener head is now closed (to the position shown in Figures 27-30) by rotating the lever 136 proximally which is shown in two stages in Figures 21 and 22. As seen in comparing Figures 20, 21, and 22, as the lever 136 is rotated proximally, the teeth 140 on the lever 136 engage the teeth 134 on the cam 122 causing the cam 122 to rotate distally. This action causes the curved slot 130 to rotate in a manner which forces the cross pin 132 to move distally in the slots 146, 148. Movement of the crosspin 132 moves the cable 24 distally causing the fastener head to close. At the same time, the pivot point 120 of the lever 118 is rotated above the broad portion 118a of the lever 118. This moves the broad portion 118a above the stop 113 and places the lever 118 in a position where the broad portion 118a does not need to exit the slot 111 and can freely pass alongside the stop 113. As shown in Figure 22, the lever 118 is now operable to fire a male fastener. It will be appreciated that, until the fastening head is completely closed, movement of the firing lever 118 to pull the cable 22 is prevented by the stop 113. In addition, it will be appreciated that the crosspin coupling 126 remains stationary as the cam 122 causes the lever 118 to be rotated about this pin.

Figure 23 shows the lever 118 moved to the proximal position which pulls the cable 22 proximally and fires the male fastener

part (as shown in Figure 31). As seen best in Figure 24, when the firing lever is in the proximal position, the stop 113 is located below the broad portion 118a. It will be appreciated that this position of the lever 118 will prevent the lever 136 from being moved distally. Distal movement of the lever 136 will attempt to rotate the cam 122 in a manner which will move the lever 118 in a direction where its broad portion 118a must pass the stop 113. Therefore, before the lever 136 can be moved to open the fastener head, the firing lever 118 must be moved back to the position shown in Figure 22. As show in Figures 23 and 24, the lever 118 is preferably concave along its proximal side so that it can be moved over the lever 106.

Turning now to Figures 25-37, the presently preferred end effector and fasteners are similar to those described above with reference to Figures 1-10 with some differences which will become apparent from the following description.

The end effector 200 has a substantially cylindrical stationary member 202, a rotatable fastener head 204, and a grasper 206. The stationary member 202 has a relatively flexible proximal portion 208 and a relatively rigid distal portion 210. The distal portion 210 has a flattened part 212 which angles down toward the distal end 214 of the stationary member 202. The

flattened part 212 is provided with a first grasping surface 216 and the grasper 206 is provided with a second grasping surface 218. A male fastener exit port 220 is located intermediate of the flattened part 212 and the proximal portion 208. As seen best in Figures 30 and 31, a firing member 222 with a movable male fastener part holder 224 is located inside the stationary member 202. As seen best in Figure 29, a store 226 of male fastener parts 227 is located inside the stationary member 202, proximal of the firing member 222. Individual male fastener parts 227a are biased from the store into the male fastener part holder 224 by a spring 229 as shown in Figure 30. According to this embodiment, up to six male fastener parts are held in the store. As seen best in Figures 28 and 29, an endoscope port 228 is provided in the stationary member 222 below the male fastener part store 226. Three cable ports 230, 232, 234 are provided in the stationary member 202 as shown in Figure 29 for attaching control cables to the grasper 206, the fastener head 204, and the firing member 222, respectively.

The rotatable fastener head 204 includes a store 236 of female fastener parts 237 and a movable tray 238 for moving female fastener parts out of the store and into position to receive a male fastener part as described below. According to this embodiment, up to six female fastener parts are held in the store.

The movable tray 238 is coupled to the fastener head 204 by flanges 238a, 238b which slideably engage grooves 204a, 204b in the fastener head as seen best in Figures 27-30. The movable fastener head 204 is coupled to the distal end 214 of the stationary member 202 by a pivot axle 240, and a hinged link 242 (Figure 28) couples the fastener head 204 to a control cable (not shown). When the link 242 is moved distally, the fastener head 204 is moved to the closed position as shown in Figure 28. When in this position, the hinge 242a in the link 242 is moved past the center of the pivot axle 240 which locks the fastener head in the closed position. The sliding tray 238 is coupled via a flange 238c and a pivoting link 244 to the pivot axle 240 as seen best in Figures 25 and 26. This link 244 causes the tray 238 to slide from the position shown in Figures 25 and 26 to the position shown in Figures 27 and 28 when the fastener head 204 is closed.

The firing member 222 is coupled to the stationary member 202 by the same pivot axle 240 as the fastener head as shown in Figures 25, 26, 30, 33, and 34. The firing member 222 is coupled to a control cable (not shown) by a lower flange 222a as shown in Figures 30, 33, and 34. As shown in Figure 32, the distal portion 210 of the stationary member 202 is provided with a stepped port 234 through which the control cable for the firing member passes and which holds the cable sheath. When the control cable pulls

the flange 222a proximally, the firing member 222 is moved towards the exit port 220. The movable male fastener part holder 224 is provided with a proximal flange 224a which is coupled to a lateral portion 210a of the stationary member 202 by a pivoting link 246 as seen best in Figure 30. This link 246 causes the holder 224 to slide distally as shown in Figure 31 when a male fastener part is fired. The purpose of the holder 224 is to prevent the male fastener part from falling out through the port 220 when the fastener head is open and to allow the firing operation to be aborted while retaining the male fastener part.

As seen best in Figures 33 and 34, the grasper 206 is pivotally coupled to the distal end of the firing member 222 on a pivot axle 250. The grasper 206 is also coupled to a control cable (not shown) via a hole 252 located above its pivot connection. As shown in Figures 31 and 32, the distal portion 210 of the stationary member 202 is provided with a stepped port 230 through which the control cable for the grasper passes and which holds the cable sheath. When the control cable is pulled proximally, the grasper is moved to the closed position shown in Figure 25.

Turning now to Figures 35-37, the presently preferred male fastener part 227 (substantially the same as the fastener part 46

described above) has a disk shaped base 227a, a central upstanding shaft 227b, and tapered barb 227c at the end of the shaft. The presently preferred female fastening member 237 is a substantially flat rectangular member 237a defining a central hole 237b. The hole 237b has a tapered entry 237c and four radial strain relief slots 237d. Four flexible or frangible peripheral tabs 237e are provided on the periphery of the rectangular member. These tabs hold the fastener part in the tray 238 as shown in Figure 35, but allow it to be pulled out of the tray after it is coupled to a male fastener part as shown in Figure 37.

Turning now to Figures 38-48, an alternate preferred end effector 300 is similar to the end effector 200 described above, with similar reference numerals referring to similar parts.

The end effector 300 has a substantially cylindrical stationary member 302, a rotatable fastener head 304, and a grasper 306. The stationary member 302 has a flattened part 312 which angles down toward the distal end 314 of the stationary member 302. The flattened part 312 is provided with a first grasping surface 316 and the grasper 306 is provided with a second grasping surface 318. A male fastener exit port 320 is located at the proximal end of the flattened part 312. As seen best in

Figures 38-44, a firing member 322 with a male fastener part holder 324 is located inside the stationary member 302.

As seen best in Figures 41-44, the holder 324 has a pair of flanged springy arms 324a, 324b which hold the base of a male fastener part, e.g. 327a. The arms 324a, 324b are biased outward to the position shown in Figure 43. As seen best in Figures 41 and 44, the interior of the stationary member 302 has contoured walls 303a, 303b which hold the arms 324a, 2324b close together, securing the male fastener part. When the firing member 322 is raised into the firing position, as shown in Figures 40 and 44, the springy arms 324a, 324b move outward as shown in Figure 43, thereby releasing the male fastener part.

As seen best in Figures 38-40, a store 326 of male fastener parts 327a, 327b, etc. is located inside the stationary member 302, proximal of the firing member 322. Individual male fastener parts 327a, 327b, etc. are biased from the store into the male fastener part holder 324 by a spring (not shown). According to this embodiment, a leaf spring 325 having an upstanding flange 325a and a distal tongue 325b (Figure 40) is arranged beneath the row of male fastener parts in the store 326. As shown in Figure 40, the distal most fastener part is prevented from exiting the store 326 by the flange 325a when the firing member 322 is in the

firing position. When the firing member 322 returns from the firing position as seen in Figures 38 and 39, the tongue 325b of the leaf spring is depressed by the firing member 322 and the flange 325a is thereby moved away from the next fastener part allowing it to enter the holder 324 of the firing member 322.

As seen best in Figures 41, 44, and 48, an endoscope port 328 is provided in the stationary member 322 below the male fastener part store 326. Three cable ports 330, 332, 334 are provided in the stationary member 302 as shown in Figures 41 and 44 for attaching control cables to the grasper 306, the fastener head 304, and the firing member 322, respectively.

As shown in Figures 41-48, the rotatable fastener head 304 includes a store 236 of female fastener parts 337 and a movable tray 338 for moving female fastener parts out of the store and into position to receive a male fastener part as described below. According to this embodiment, up to six female fastener parts are held in the store. As seen best in Figure 44, the movable tray 338 is coupled to the fastener head 304 by flanges 338a, 338b which slideably engage flanges 304a, 304b in the fastener head. The sliding tray 338 is coupled via a flange 338c and a pivoting link 344 to the pivot axle 340 as seen best in Figures 44, 45, and 48. This link 344 causes the tray 338 to slide from the position

shown in Figure 44 to the position shown in Figures 45 and 48 when the fastener head 304 is closed.

As seen best in Figures 45-48, the female fastener parts 337a-337e are biased out of the store 336 by a bifurcated leaf spring 305 and are held laterally in line by a support post 307 which is seen best in Figure 46 where the movable tray has been removed to better expose the spring 305 and the post 307. A fastener discharge spring 309 is located adjacent to the female fastener store 336 and is provided with a male fastener engaging surface 311. As the fastener head 304 is moved from the open position shown in Figure 46 to the closed position shown in Figure 45, the movable tray 338 moves the top most female fastener part 337a out of the store and over the discharge spring 309. Figure 47 shows the tray 338 in a midway position as the fastener 337a is being moved into position to receive a male fastener part. When a male fastener is fired into the female fastener as shown in Figure 48, The end of the male fastener will engage the surface 311 on the spring 309 and compress the spring. It will be appreciated that as the firing member 322 is returned from the firing position, the spring 309 will push against the end of the male fastener thereby pushing the female fastener out of the tray, bending or breaking the tabs of the female fastener.

The firing member 322 is coupled to the stationary member 302 by the same pivot axle 340 as the fastener head as shown in Figures 39, 40, 42, 43 and 48. The firing member 322 is coupled to a control cable (not shown) by a lower flange 322a as shown in Figure 48. When the control cable pulls the flange 322a proximally, the firing member 322 is moved towards the exit port 320.

There have been described and illustrated herein several embodiments of a flexible endoscopic surgical instrument for invagination and fundoplication. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.